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UNCLAS ZAGREB 002268

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USDOC FOR 4232/ITA/MAC/EUR/OEERIS/CEED/MROGERS USDOC FOR 3150/USFCS/OIO/EUR/CEENIS/PBRADLEY

E.O. 12958: N/A TAGS: <u>ETRD KIPR HR</u>

SUBJECT: USDOC VISIT STEPS UP HEAT ON CROATIA OVER

INTELLECTUAL PROPERTY MOU

REF: ZAGREB 2176

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Summary

11. (SBU) USDOC Market Access and Compliance Office Director, Susanne Lotarski, delivered a strong message to the Croatian government to forward the long-stalled bilateral MOU on intellectual property rights. During an October 14-15 visit to Zagreb, she urged authorities to ratify the MOU or face possible trade sanctions under the U.S. Special 301 process. Lotarski also emphasized the relation between strong IP protection, business ethics and rule-of-law -- all of which investors judge when evaluating a country. Her warning came on the heels of a similarly forceful warning by the Ambassador, most recently with Deputy Prime Minister Simonic (reftel). End Summary.

"Ashamed" MOU Did Not Move Forward

12. (SBU) In her October 14 meeting with Minister of Economy Ljubo Jurcic, Lotarski noted that a lack of progress on the part of the Croatian government on the intellectual property memorandum of understanding endangered some of the positive aspects of the bilateral relationship. She said the U.S. is disappointed in the failure of the government to include data exclusivity in the recent drug law -- especially since protection of confidential test data is required by the WTO and the

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- EU. There was a good chance Croatia would be moved up on the 301 list during a fall out-of-cycle review. This was an escalation in a process that could lead to trade sanctions, such as removal of GSP benefits -- and not only on pharmaceuticals.
- 13. (SBU) Jurcic said the Ministry of Economy supported WTO principles and the U.S. position on the MOU. The Ministry of Health, on the other hand, supported Croatian pharmaceutical producers and Croatian consumers. However, the visit of the Ambassador to the Deputy Prime Minister and the delivery of the non-paper had made an impression on the government, and the issue was being revisited.
- 14. (SBU) Acting Deputy Economy Minister Olgica Spevec, also at the meeting, recalled that she had assured the Embassy last fall that the MOU would probably make it to the parliament early in 2003. She was frankly ashamed that the GOC had not lived up to its obligations, and noted that lately the Ministry of Economy had been left out of meetings on this issue, perhaps because the government did not like its stance. Spevec asked whether the U.S. would consider amending the agreement, or at least adding a phase-in period. We noted that the phase in contemplated in the MOU had already expired in 1999. Lotarski reported that all EU accession countries had accepted strong IP provisions. Even Poland, with whom we had had the most trouble, had implemented data exclusivity, if not for as long a period as we would like.

MOH: Cheap Drugs the Priority

15. (SBU) Lotarski met the same day with Minister of Health, Ivo Vlahusic, and Director of Drug Approvals, Csaba Dohoszky, to deliver the same message. Vlahusic was forthright in saying that as Minister of Health, with primary responsibility for the welfare of Croatians, he had to oppose the MOU. However, as a member of the ruling coalition, if the government told him to go along with the MOU, he would. (Note: the Ministry of Health did indeed allow data exclusivity

language to be inserted into the recent drug law. It was, we were told, a call from Pliva to the Prime Minister that resulted in the yanking of that provision.)

16. (SBU) Dohoszky asserted that "Croatia is not the only country where intellectual property protection is not what the big multinationals want." While Croatia did not face the same problems that under-developed countries did, generics are still vital to its health system. Lotarski countered that the USG was not anti-

generic, but it did demand a level playing field. It was not fair that an innovative company had to submit test data, which was then used by a generics company as a basis for the latter's registration. To add insult to injury, in Croatia, the (Croatian) generics company was likely to get its registration months, sometimes years, before the innovative company for the same drug, while benefiting from the innovative company's test data. It came down to whether Croatia wanted to be known as a country with good business ethics and rule-of-law.

- 17. (SBU) Lotarski also pointed out that Croatia had received U.S. support for its WTO entry in return for the MOU. "It would be fair to ratify the MOU, Vlahusic admitted, adding, however, that the promise to ratify the MOU in exchange for your support for our WTO entry was an "oral agreement." Nevertheless, the Minister promised to contact the Croatian pharmaceutical industry and ask whether it would maintain its position in the face of possible trade sanctions. He would also consult with the MFA and the government. Commercial Counselor Beryl Blecher urged Vlahusic to meet with the foreign pharmaceutical producers as well.
- 18. (SBU) Dohoszky highlighted a problem that he said could be more acute than data exclusivity that is, "retroactive patent protection," otherwise known as pipeline protection. "We all know that data exclusivity is inevitable, but this pipeline protection could really bust the health care budget if there is a big retroactive effect." Would it be possible, the drug approval director asked, to modify the MOU or add a supplement to take the sting out of the pipeline protection provision? Lotarski citing the importance of pipeline protection to the U.S., reported that Hungary had raised the same objections, but resolved its issues.

MFA Will Try to Push Rock Back Up Hill

- 19. (SBU) Lotarski met also with Drazen Margeta, MFA Assistant Minister for Non-European countries. Margeta emphasized the importance the GOC placed on its relationship with the U.S., highlighting recent joint military exercises. Lotarksi described the threat that the failure to forward the MOU to the parliament posed to the relationship. Margeta said his Ministry would try to forward the MOU to the Cabinet for approval --again. The MFA completed the procedure earlier this year, only to have the MOU shelved at the Cabinet level, apparently because of opposition from Croatian industry.
- 110. (SBU) Miro Kovacic, head of the Americas Desk, also said that pipeline protection had been raised as an important issue by Croatian drug makers. They were floating the figure of 100 million euro as the extra cost to the Croatian health system of data exclusivity and pipeline protection. Lotarski noted that other Central European countries had been asked to provide this protection, and found it worthwhile, when looking at the overall economic effect. Competition and the health care system suffered if innovative drug makers did not want to bring new drugs into the market. At the end of the day, a country could not use theft to balance its health care books, and a country had to live up to its word, even when governments changed.

MOU is Not EU Accession Problem

111. (SBU) Lotarski's final meeting was with Orsat Miljenic, Deputy Minister of EU Integration. Miljenic noted that the Ministry saw no reason to object to ratification of the MOU. Updated intellectual property protections were clearly required by the EU, and his ministry wanted to meet EU standards as soon as possible — regardless of Croatia's EU accession date. Convergence with EU standards wase good for Croatia regardless, he said, noting that Croatia aspired to be a "virtual member" of the EU, even before entry.

Comment and recommendation

112. (SBU) With elections expected on November 23, action on the MOU is unlikely in the very short term, but a new government could take up the issue in January. Although the Parliament was dissolved on October 17 in

anticipation of elections, we would like to see the new government -- which will likely be in place by early January -- act on this issue quickly. Only increased outside pressure will move this issue forward in the face of fierce resistance from the local generics manufacturers. To keep up the pressure, we would recommend accepting an out-of-cycle U.S. industry petition for Croatia and urge that Washington agencies move Croatia to the Priority Watch List.

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